CLAIM AMENDMENTS

1. (Currently amended) A method of treating a painful episode due to a sickle cell disease in a patient in need of such treatment, which method comprises administering to the patient a buprenorphine transdermal system (BTDS) as a monotherapy treatment.

2. (Original) The method of claim 1, comprising administering BTDS 5 within two days after the onset of the painful episode.

3. (Original) The method of claim 1, wherein the administering of the BTDS results in a reduction of the pain experienced by the patient by at least 1 point on an 11 point pain scale.

4. (Currently amended) A method of treating a painful episode due to a sickle cell disease in a patient in need of such treatment, which method comprises:

administering to the patient a first buprenorphine-containing transdermal dosage form as a monotherapy treatment for a first dosing period;

administering to the patient a second buprenorphine-containing transdermal dosage form as a monotherapy treatment for a second dosing period, wherein the second dosage form comprises the same dosage of buprenorphine as, or a greater dosage of buprenorphine than, the first dosage form; and

administering to the patient a third buprenorphine-containing transdermal dosage form as a monotherapy treatment for a third dosing period, wherein the third dosage form comprises a greater dosage of buprenorphine than the second dosage form.

5. (Original) The method of claim 4, further comprising extended subsequent dosing periods with subsequent dosage forms for a given time period as needed by the patient to achieve desired analgesia.

6. (Original) The method of claim 4, wherein the first dosing period is at least 2 days.

7. (Original) The method of claim 4, wherein the second dosing period is at least 2 days.

8. (Original) The method of claim 4, wherein the third dosing period is at least 5 days.

9. (Original) The method of claim 4, wherein the first dosage form comprises 5 mg of buprenorphine.

10. (Original) The method of claim 4, wherein the second dosage form comprises 10 mg of buprenorphine.

11. (Original) The method of claim 4, wherein the third dosage form comprises 20 mg of buprenorphine.

12. (Original) The method of claim 4, wherein the third dosage form comprises 30 mg of buprenorphine.

13. (Original) The method of claim 4, wherein the third dosage form comprises 40 mg of buprenorphine.

14. (Currently amended) A method of treating a painful episode due to sickle cell anemia in a patient in need of such treatment, which method comprises:

administering to the patient BTDS 5 as a monotherapy treatment for 3 days;

administering to the patient BTDS 10 as a monotherapy treatment for 3 days; and

administering to the patient BTDS 20 as a monotherapy treatment for 7 days.

15. (Original) The method of claim 14, further comprising extended subsequent dosing periods with subsequent BTDS 20 dosage forms for a given time period as needed by the patient to achieve desired analgesia

16. (Currently amended) A method of treating a painful episode due to sickle cell anemia in a patient in need of such treatment, which method comprises administering to the patient BTDS 10 as a monotherapy treatment for 7 days with subsequent BTDS 20 as a monotherapy treatment dosage forms for a given time period as needed by the patient to achieve desired analgesia.

17. (Original) The method of claim 1, wherein the patient is a child.

18. (Original) The method of claim 1, wherein the patient is an adult.

19. (Original) The method of claim 1, wherein the sickle cell disease is sickle cell anemia.

20. (Original) The method of claim 1, wherein the sickle cell disease is hemoglobin SC disease or hemoglobin S-β-thalassemia.

21. (Original) The method of claim 1, wherein the transdermal dosage form is selected form the group consisting of transdermal dosage article and transdermal dosage composition.

22. (Original) The method of claim 21, wherein the transdermal dosage article is a diffusion-driven transdermal system.

23. (Original) The method of claim 21, wherein the transdermal dosage composition is selected from the group consisting of a topical gel, a lotion, an ointment, a transmucosal system, a transmucosal device, and an iontophoretic delivery system.

24. (Currently amended): A method of treating a painful episode due to sickle cell anemia in a patient in need of such treatment, which method comprises

administering intravenously to the patient an effective amount of opioid for an initial part of the painful episode; and

administering to the patient at least one BTDS as a monotherapy treatment for the remainder of the painful episode, while reducing the amount of the opioid administered intravenously.

25. (Original) The method of claim 24, wherein the initial part is no more than 3 days.

26. (Original) The method of claim 24, wherein the at least one BTDS is a BTDS 5.

27. (Original) The method of claim 24, wherein the at least one BTDS comprises a BTDS 5 for 3 days; a BTDS 10 for 3 days; and a BTDS 20 for 7 days.

28. (Original) The method of claim 24, wherein the opioid is a member of the group consisting of buprenorphine, morphine, hydromorphone, oxycodon, tramadol, oxymorphone, dihydrocodein, and hydrocodon.

29. (New) A method of treating a painful episode due to sickle cell disease in a patient in need of such treatment, which method comprises administering to the patient a buprenorphine transdermal system (BTDS) in combination with a mu agoinst opioid or a mixed agonist/antagonist opioid.

30. (New) The method of claim 29, which comprises administering BTDS 5 within two days after the onset of the painful episode.

31. (New) The method of claim 29, which further comprises:

administering to the patient a first buprenorphine-containing transdermal dosage form for a first dosing period;

administering to the patient a second buprenorphine-containing transdermal dosage form for a second dosing period, wherein the second dosage form comprises the same dosage of buprenorphine as, or a greater dosage of buprenorphine than, the first dosage form; and

administering to the patient a third buprenorphine-containing transdermal dosage form for a third dosing period, wherein the third dosage form comprises a greater dosage of buprenorphine than the second dosage form.

32. (New) The method of claim 31, which further comprises administering subsequent dosing periods with subsequent buprenorphine dosage forms for a given time period as needed by the patient to achieve analgesia.

33. (New) The method of claim 31, wherein the first dosing period is at least 2 days.

34. (New) The method of claim 31, wherein the second dosing period is at least 2 days.

35. (New) The method of claim 31, wherein the third dosing period is at least 5 days.

36. (New) The method of claim 31, wherein the first dosage form comprises 5 mg of buprenorphine.

37. (New) The method of claim 31, wherein the second dosage form comprises 10 mg of buprenorphine.

38. (New) The method of claim 31, wherein the third dosage form comprises 20 mg of buprenorphine.

39. (New) The method of claim 31, wherein the third dosage form comprises 30 mg of buprenorphine.

40. (New) The method of claim 31, wherein the third dosage form comprises 40 mg of buprenorphine.

41. (New) A method of treating a painful episode due to sickle cell anemia in a patient in need of such treatment, which method comprises:

administering to the patient BTDS 5 for 3 days;

administering to the patient BTDS 10 for 3 days; and

administering to the patient BTDS 20 for 7 days;

wherein at least one BTDS is administered in combination with a mu agoinst opioid or a mixed agonist/antagonist opioid.

42. (New) The method of claim 41, which further comprises administering subsequent dosing periods with subsequent BTDS 20 dosage forms for a given time period as needed by the patient to achieve analgesia

43. (New) A method of treating a painful episode due to sickle cell anemia in a patient in need of such treatment, which method comprises administering to the patient BTDS 10 for 7 days with subsequent BTDS 20 dosage forms for a given time period as needed by the patient to achieve desired analgesia, wherein at least one BTDS dosage form is administered in combination with a mu agoinst opioid or a mixed agonist/antagonist opioid.

44. (New) The method of any one of claims 31, 41 or 43, wherein the mu agoinst opioid or mixed agonist/antagonist opioid is selected from the group consisting of: morphine, hydromorphone, oxycodone, tramadol, oxymorphone, dihydrocodeine, and hydrocodone.

45. (New) A method of treating a painful episode due to sickle cell disease in a patient in need of such treatment, which method comprises administering to the patient a buprenorphine transdermal system (BTDS) in combination with a non-steroidal anti-inflammatory drug (NSAID) or acetominophen.

46. (New) The method of claim 45, which comprises administering BTDS 5 within two days after the onset of the painful episode.

47. (New) The method of claim 45, which further comprises:

administering to the patient a first buprenorphine-containing transdermal dosage form for a first dosing period;

administering to the patient a second buprenorphine-containing transdermal dosage form for a second dosing period, wherein the second dosage form comprises the same dosage of buprenorphine as, or a greater dosage of buprenorphine than, the first dosage form; and

administering to the patient a third buprenorphine-containing transdermal dosage form for a third dosing period, wherein the third dosage form comprises a greater dosage of buprenorphine than the second dosage form.

48. (New) The method of claim 45, which further comprises administering subsequent dosing periods with subsequent buprenorphine dosage forms for a given time period as needed by the patient to achieve analgesia.

49. (New) The method of claim 45, wherein the first dosing period is at least 2 days.

50. (New) The method of claim 45, wherein the second dosing period is at least 2 days.

51. (New) The method of claim 45, wherein the third dosing period is at least 5 days.

52. (New) The method of claim 45, wherein the first dosage form comprises 5 mg of buprenorphine.

53. (New) The method of claim 45, wherein the second dosage form comprises 10 mg of buprenorphine.

54. (New) The method of claim 45, wherein the third dosage form comprises 20 mg of buprenorphine.

55. (New) The method of claim 45, wherein the third dosage form comprises 30 mg of buprenorphine.

56. (New) The method of claim 45, wherein the third dosage form comprises 40 mg of buprenorphine.

57. (New) A method of treating a painful episode due to sickle cell anemia in a patient in need of such treatment, which method comprises:

administering to the patient BTDS 5 for 3 days;

administering to the patient BTDS 10 for 3 days; and

administering to the patient BTDS 20 for 7 days;

wherein at least one BTDS is administered in combination with a non-steroidal anti-inflammatory drug (NSAID) or acetominophen.

58. (New) The method of claim 57, which further comprises administering subsequent dosing periods with subsequent BTDS 20 dosage forms for a given time period as needed by the patient to achieve analgesia

59. (New) A method of treating a painful episode due to sickle cell anemia in a patient in need of such treatment, which method comprises administering to the patient BTDS 10 for 7 days with subsequent BTDS 20 dosage forms for a given time period as needed by the patient to achieve desired analgesia, wherein at least one BTDS dosage form is administered in combination with a non-steroidal anti-inflammatory drug (NSAID) or acetominophen.

60. (New) The method of any one of claims 31, 41 or 43, wherein the NSAID is ibuprofen or aspirin.